IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No.: 07-807-JJF-LPS **REDACTED VERSION DI 20**

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO DISMISS
SANDOZ'S COUNTERCLAIM NOS. 4-9

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Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") move to dismiss Sandoz Inc.'s Counterclaim Nos. 4-9 (D.I. 12) for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

I. THE NATURE AND STAGE OF THE PROCEEDING

AstraZeneca has sued Sandoz Inc. ("Sandoz") for infringement of U.S. Reissue Patent RE37,314 ("the '314 patent") under 35 U.S.C. § 271(e)(2)(A) and for a declaratory judgment under 35 U.S.C. § 271(a) based on threatened infringement. The action results from Sandoz filing Abbreviated New Drug Application ("ANDA") No. 79-171 with the United States Food and Drug Administration ("FDA"), and Sandoz's certification to the FDA that it intends to market generic versions of AstraZeneca's highly successful drug CRESTOR® before the '314 patent expires.

Sandoz is one of seven generic pharmaceutical companies to so challenge the '314 patent. In an effort to resolve the multiple challenges to its patent rights, AstraZeneca filed seven related patent infringement actions, including this action, in the District of Delaware on December 11, 2007 (C.A. Nos. 07-805, 07-806, 07-807, 07-808, 07-809, 07-810, and 07-811). The Complaint in each action alleges infringement of the '314 patent as noted above. In its Answer, Affirmative Defenses and Counterclaims of Defendant Sandoz Inc. (D.I. 12), Sandoz raised counterclaims requesting declaratory judgment of invalidity and noninfringement of three patents not asserted by AstraZeneca—U.S. Patent Nos. 6,316,460 ("the '460 patent"), 6,858,618 ("the '618 patent"), and 6,589,959 ("the '959 patent"). The '460 and '618 patents are listed in "Approved Drug Products with Therapeutic Equivalence Evaluations," (commonly called "the Orange Book"), while the '959 patent is not. *See* 21 C.F.R. § 314.53(e). This motion seeks to dismiss those counterclaims.

II. SUMMARY OF ARGUMENT

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the '959 patent is not listed in the Orange Book and, thus, 35 U.S.C. § 271(e) does not and cannot provide subject matter jurisdiction for declaratory judgment jurisdiction. Under a traditional declaratory judgment jurisdiction analysis, there is no case or controversy on which to base declaratory judgment jurisdiction, because AstraZeneca has not asserted or threatened to assert the '959 patent against Sandoz.

III. STATEMENT OF FACTS

This case relates to AstraZeneca's CRESTOR® pharmaceutical product, and Sandoz's efforts to sell a generic version of CRESTOR® before expiration of the pioneer patent on the active ingredient, rosuvastatin calcium. On November 8, 2007, Sandoz notified AstraZeneca of its ANDA and intentions to obtain FDA approval to engage in the manufacture, importation, use or sale of rosuvastatin calcium before expiration of the '314 patent (covering the active ingredient in CRESTOR®), the '460 patent (covering certain drug formulations containing that active ingredient), and the '618 patent (covering a method of using the active ingredient to treat certain patient populations), alleging that these patents are invalid, unenforceable, and/or will not be infringed. In response to this notification, AstraZeneca filed suit against Sandoz.

In its Complaint, AstraZeneca only asserted infringement of the '314 patent. (D.I. 1.) In its Answer, Affirmative Defenses and Counterclaims, however, Sandoz counterclaimed for declaratory judgment of non-infringement and invalidity of the unasserted '460 and '618 patents.

(D.I. 12 ¶¶ 72-79.) Sandoz also counterclaimed for declaratory judgment of non-infringement and invalidity of the unasserted '959 patent (covering a certain crystal form of CRESTOR®'s active ingredient). *Id.* at paras. 80-83.

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AstraZeneca now moves to dismiss Sandoz's Counterclaim Nos. 4-9 regarding the validity and infringement of the '460, '618, and '959 patents for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

IV. ARGUMENT

> Pursuant to Federal Rule of Civil Procedure 12(b)(1), the Court is authorized to dismiss a complaint, or in this case, a counterclaim, if the Court lacks subject matter jurisdiction over the claims alleged. … Once the Court's subject matter jurisdiction over a counterclaim is challenged, the counterclaim plaintiff bears the burden of proving that jurisdiction exists.

Pfizer, Inc. v. Ranbaxy Labs. Ltd, 525 F. Supp. 2d 680, 684 (D. Del. 2007) (citations omitted). To establish jurisdiction under the Declaratory Judgment Act, Sandoz bears the burden of proving that the facts alleged "under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007).

REDACTED

REDACTED

In *Pfizer*, Pfizer brought suit against Ranbaxy on two Orange Book-listed patents. 525 F. Supp. 2d at 683-84.

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Ranbaxy's counterarguments regarding the prospect of future litigation related to the potential reissue patent were unavailing, as the Court found those claims "speculative, purely hypothetical and unripe for judicial determination." *Id.* at 686-87; *see also id.* at 687 (advisory opinions are "wholly inconsistent with the most basic precepts of jurisdictional jurisprudence"). **REDACTED**

[1] The Federal Circuit had declared a claim of the unasserted patent invalid in previous litigation between the parties, and Pfizer sought reissue of that patent to correct errors in the claims. *Pfizer*, 525 F. Supp. 2d at 683-84.

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2. Absent Affirmative Acts by AstraZeneca, Declaratory Judgment Jurisdiction Over Claims Related to the '959 Patent Cannot Lie

Unlike the '460 and '618 patents, the '959 patent is not listed in the Orange Book. This distinction is important, because declaratory judgment jurisdiction under 35 U.S.C. § 271(e) applies only to Orange Book listed patents. This tenet holds true for jurisdiction under both § 271(e)(2) and § 271(e)(5).

For instance, in *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1009 n.4 (N.D. Ill. 2001), the court decided that § 271(e)(2)(A) "applies to 'listed' drugs only, meaning drugs

listed in the [the Orange Book]." *See also Watson Pharms, Inc. v. E. Henney, M.D.,* 194 F. Supp. 2d 442, 444 (D. Md. 2001) ("One of the important aspects of the FDA's listing of a patent in the Orange Book arises from the patent challenge procedures under the Hatch-Waxman Amendments. That is, listing triggers the right of the patent holder to sue the generic's maker for patent infringement, which carries with it a stay of the FDA's approval of the ANDA for up to 30 months, pending resolution of the patent challenge. *See* 35 U.S.C. section 271(e)(2)(A)."). Declaratory judgment jurisdiction under § 271(e)(5) is similarly tied to Orange Book listed patents, as that section only provides jurisdiction over patents included in the ANDA filer's certification to the FDA. 35 U.S.C. § 271(e)(5) ("where … an [ANDA] application … includes a certification … , and [] the owner of the patent that is the subject of the certification … [did not bring] an action for infringement of such patent … [courts shall have declaratory judgment jurisdiction]."). Notably, the FDA only requires certification against Orange Book listed patents. 21 U.S.C. § 355(j)(2)(A)(vii). Thus, it is no surprise that Sandoz did not certify against the '959 patent and that, consequently, claims related to that patent fall outside the ambit of § 271(e)(5).[2]

Because the '959 patent counterclaims lie outside the statutory framework of § 271(e), jurisdiction over those claims must be analyzed like any other declaratory judgment patent claim—under the totality of the circumstances.[3] *MedImmune*, 127 S. Ct. at 771, 774 n.11

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[2] Although in its Answer, Affirmative Defenses, and Counterclaims, Sandoz alleges that it certified to the FDA that the '959 patent was invalid, unenforceable, or not infringed. (D.I. 12 at ¶63.) The notice Sandoz provided to AstraZeneca included no such certification.

[3] Inasmuch as the **REDACTED** cases, discussed *supra*, each dealt with Orange Book listed patents and declaratory judgment jurisdiction under § 271(e), they are not applicable to jurisdiction over claims related to the '959 patent.

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(overruling the Federal Circuit's test for determining declaratory judgment jurisdiction in a patent case and reemphasizing the totality of the circumstances test). In its first decision applying *MedImmune*, the Federal Circuit made clear that, in a circumstance like the present one, declaratory judgment jurisdiction requires an affirmative act by the patentee.

> In the context of conduct prior to the existence of a license, declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.

SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380-81 (Fed. Cir. 2007). Here, AstraZeneca committed no affirmative act giving rise to declaratory judgment jurisdiction. Importantly, AstraZeneca has neither asserted nor threatened to assert the '959 patent against Sandoz. AstraZeneca has not met with Sandoz, has sent no correspondence indicating that the '959 patent is a "patent of interest," has not offered or pushed any license agreement, has not provided Sandoz with infringement claim charts or indicated the existence thereof, and has not initiated settlement discussions. *Cf. id.* at 1374-76. In fact, the only "act" related to the '959 patent that Sandoz can charge AstraZeneca with is the delisting of that patent from the Orange Book. Accordingly, Sandoz's *perception* that the '959 patent *may* pose a risk of infringement is insufficient to create a case or controversy between the parties. *Id.* at 1380-81.[4]

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[4] This situation is, therefore, distinguishable from the currently pending motions in related cases by the Cobalt, Sun, Apotex, and Aurobindo defendants to dismiss AstraZeneca's counts under 35 U.S.C. § 271(a) that seek declaratory judgments of patent infringement. In each of those cases, the defendants affirmatively certified to the FDA and AstraZeneca that they will sell generic rosuvastatin calcium before expiration of the '314 patent, an Orange Book listed patent on which AstraZeneca has sued each of the defendants. Under those circumstances, there is an actual case or controversy.

V. CONCLUSION

For the forgoing reasons, AstraZeneca respectfully requests that this Court follow its recent decisions in similar disputes, and dismiss Sandoz's Counterclaim Nos. 4-7 for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). Additionally, AstraZeneca respectfully requests dismissal of Sandoz's Counterclaim Nos. 8-9 regarding the '959 patent, because Sandoz cannot demonstrate any affirmative acts by AstraZeneca that indicate the presence of a case or controversy related thereto.

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CERTIFICATE OF SERVICE

I hereby certify on this 28th day of March, 2008 I electronically filed the foregoing Redacted Version DI 20 PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO DISMISS SANDOZ'S COUNTERCLAIM NOS. 4-9 with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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EXHIBIT 1
FULLY REDACTED